

9/15/02

Continued Prosecution Application

1. The request filed on May 21, 2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/459,022 is acceptable and a CPA has been established. An action on the CPA follows.

Status of the Claims

2. Claims 1-16 are pending, new claim 17 has been added, and claims 1-17 are examined in the instant application. An initialed copy of Applicant's form 1449 is attached.
3. All rejections not discussed below have been withdrawn.

Information Disclosure Statement

4. Applicant's Information disclosure statement, paper number 10, filed August 6, 2001, has been entered.

Claim Rejections - 35 USC § 112-second paragraph

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
6. Claims 1-17 are rejected as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1:

- After step (a) of claim 1, an Agrobacterium-inoculated explant was produced.

Step (b) should recite what to do with the Agrobacterium-inoculated explant, not with the Agrobacterium.

- Where did the "transformed cell line" come from?

In claims 6, 7, 8 and 9, "the moisture-limitation or removal period" lacks antecedent basis.

Clarification or correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification,

- while being enabling for adding 100–300 microliters of water during the coculturing step,

does not reasonably provide enablement for

- all conditions that decrease the weight of Agrobacterium inoculated explants.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant's invention related to a rapid transformation and regeneration system for plants. In particular, the inventions relates to a plant tissue preparation system.

The breadth of applicant's claims encompass all conditions know to decrease weight of an explant, with no upper limits on the amount of weight lost, including physical removal of plant tissue from the experiment.

Applicant shows adding water in an amount of 100-300 microliters, at the coculturing step, will result in increased number of Gus spots, indicative of increased transformation efficiency.

The state of the art indicates that it is unpredictable as to what methods of decreasing the weight of the explant would increase transformation efficiency. It is unpredictable what amount of water should be added to the coculturing medium to decrease the weight of the explant. In fact, Table 3 (p 21-22. specification) shows that only the 100-300 microliters water addition conditions increased transformation efficiency. When no water was added, the weight of the explant decreased, but no increase in transformation was observed. Furthermore, while the 100-300 microliters water addition condition increased the transformation efficiency, none of the water additions resulted in a 30-50% weight decrease of the explant as recited in the claims. The percent of weight decrease for those which showed increased transformation efficiency was 20.3-23.0%, significantly less than than Applicant's claimed 30-50%. Applicant should note that when the explant was exposed to conditions which decreased weight by 34.8%, no increased transformation efficiency was observed conditions (Table 3).

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Re the "time period of moisture removal": Applicant claims no limitation on this time period—it can be instantaneous or infinitely long. It is well known in the art that removal of moisture, especially rapid removal of moisture, can cause osmotic shock, which is deleterious, especially to plant cells (Biochemistry & Molecular Biology of Plants, Buchanan et al, eds, 2000, American Society of Plant Physiologists, Rockville, MD, p 1158). It is unpredictable that any time period would function as desired. Finding proper conditions would require a myriad of experiments and would impose undue burden on one of ordinary skill of the art. As evidence of the importance of this, applicant claims specified time periods in dependent claims 6, 7 and 8.

In view of the breadth of the claims (any plant, any conditions than decrease the weight to the explant, and any percentage weight reduction) and the lack of guidance in the specification, undue trial and error experimentations would be required to enable the invention as commensurate in scope with the claims.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 1638

10. Claims 1-10, 12 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Uze, M, et al, Plant Science 130 (1997) pages 87-95 (published July 27, 1997).

Uze teaches a method for producing a fertile transgenic rice plant (pg 94, 1st full paragraph) comprising introducing one or more genetic components (p 88, last paragraph, & continuing to p 89), coculturing rice calli (p88 1st paragraph, and Table 3)) with Agrobacterium containing the genetic component (p 90, paragraph continued from p 89) under plasmolysis conditions (p 90, paragraph continued from p 89). Uze further teaches a precultured tissue (p 89, last paragraph) and use of a one day (p 90, paragraph continued from p 89) time period for plasmolysis, after inoculation with Agrobacterium. It should be noted that plasmolysis is caused by water loss from the plant cell (Webster's dictionary, p900).

Accordingly, Uze anticipates the claimed invention.

11. Claims 1-10, 12, and 15 remain rejected under 35 U.S.C. 102(b) as being anticipated by Hiei et al, Plant Journal (1994) 6: 271-282.

Hiei teaches a method for producing a fertile transgenic rice plant (Abstract and Table 1, pg 272) comprising introducing one or more genetic components (p271, "Results", last paragraph and continuing on p272), coculturing rice calli) with Agrobacterium containing the genetic component under conditions of water removal from the explants

Hiei disclose media used in cocultivation comprising either 2N-AS or N6S3-AS (Table 5, p 278, and 5th paragraph p 280), from which explants were then transferred to

2N6-CH, 2N6K-CH or N6-S3-CH, then to culture on N6-7CH (Table 5, p 278, and 5th paragraph p 280). These differences in media composition present a higher osmotic potential in the N6-7CH medium (glucose at 20 g/L), at a later step, than in the 26-AS or N6S3-AS medium (glucose at 10 g/L), at an earlier step. It is known that water moves spontaneously from regions of lower osmotic potential to regions of higher osmotic potential (Buchanan, *op. cit.* p 1162) and further established by Applicant (specification p15). Accordingly, water has been moved from the tissue of the earlier step, decreasing the weight of the tissue, into the medium of the later step. Hiei further teaches the use of a 3 to 5 day time period for these conditions.

Accordingly, Hiei anticipates the claimed invention.

Applicant traversed, stating that the Office has not identified anywhere in Hiei a step of coculturing the Agrobacterium inoculated explant under conditions that decrease the weight of the Agrobacterium inoculated explant. To the extent that Applicant's traversal applies to the rejection above, this traversal has been addressed.

12. Claims 1, 2, 6, 7, 8, 11 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Chee, P, et al, in Agrobacterium Protocols, K. Gartland and M Davey, eds, (1995) Humana Press, Totowa, NJ, pages 101-119.

Chee teaches a method for producing a fertile transgenic soybean plant (p 118) comprising introducing one or more genetic components (p 103, Figure 1, and p 107, all), coculturing a regenerable plant tissue with Agrobacterium containing the genetic component (p 107, item (4)) under conditions that decrease the weight of the explant (p

107, item (5)). Chee further teaches a precultured tissue (p 107, all) and use of a moisture-removal period after inoculation with *Agrobacterium* where the time period is 4 days (p 107, item (5)).

Accordingly, Chee anticipates the claimed invention.

13. Claims 1-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Somerville, et al, US 5,668,292, issued September 16, 1997.

Somerville teaches a method for producing a fertile transgenic tobacco plant (column 26, lines 60-61) comprising introducing one or more genetic components (column 25 line 48, through to line 13 of column 2, and Table 3), and coculturing the explant with *Agrobacterium* containing the genetic component. Somerville further teaches soybean and corn (column 35 lines 24-28).

Somerville does not disclose conditions which decrease the weight of *Agrobacterium* inoculated explant and they do not teach adding additional water to the cocultivation medium. However, In Table 3 of Applicant's specification, when no water is added, as taught by Somerville, the explant loses weight. Therefore the method used by Somerville to produce fertile transgenic plants is inherently under conditions which would decrease the weight of the *Agrobacterium* inoculated explant. Furthermore, the weight loss of the explant with no water added is inherently not more than 50%, again as evidenced by Table 3 of Applicant's disclosure.

Accordingly, Somerville anticipates the claimed invention.

Remarks

14. No claim is allowed.
15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 703-308-7023. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Georgia L. Helmer PhD
Patent Examiner, Art Unit 1638
May 9, 2003